PSJ15 Exh 47

Message

From: Young, Jim L (Hazelwood) [Jim.Young@mallinckrodt.com]
Sent: 12/20/2013 2:13:56 PM
To: Barrett, Thomas [Thomas.Barrett@mallinckrodt.com]; Chen, Yin [Yin.Chen@mallinckrodt.com]; Crary, Amy [Amy.Crary@mallinckrodt.com]; Devarakonda, Krishna [Krishna.Devarakonda@mallinckrodt.com]; Martinez, Jose L, Dr. (Hazelwood) [Jose.Martinez4@mallinckrodt.com]; Neubert, William J [William.Neubert@mallinckrodt.com]; Sanford, Kimberly [Kimberly.Sanford@mallinckrodt.com]; Simpson, Dale J [Dale.Simpson@mallinckrodt.com]; Ward, Julie A [Julie.Ward@mallinckrodt.com]; Zheng, Yanping [Yanping.Zheng@mallinckrodt.com]; Rochon, Louise S [Louise.Rochon@mallinckrodt.com]; Bhar, Paul [Paul.Bhar@mallinckrodt.com]
Subject: FW: Mallinckrodt Daily News Report 20 December 2013

From: Mallinckrodt Daily News Report
Sent: Friday, December 20, 2013 8:14:10 AM (UTC-06:00) Central Time (US & Canada)
To: Mallinckrodt Daily News Report
Subject: Mallinckrodt Daily News Report 20 December 2013

Mallinckrodt Pharmaceuticals

Mallinckrodt Daily News Report 20 December 2013

MALLINCKRODT CORPORATE NEWS

MALLINCKRODT PRODUCT NEWS

Nuvo Research® and NovaMedica sign agreement to market Pennsaid® in Russia, PRNewswire - 19 December 2013

MALLINCKRODT COMPETITOR NEWS

Mylan's new HQ takes global approach, Observer-Reporter - 19 December 2013

Teva Pharmaceutical Industries Limited: Teva to Report Fourth Quarter 2013 Financial Results on February 6, 2014, Business Wire - 19 December 2013

Daiichi may get Japanese experts to help Ranbaxy meet USFDA norms, The Economic Times - 20 December 2013

Paladin Announces Early Termination of HSR Act Waiting Period and Canadian Competition Act Compliance in Connection with Endo Health's Proposed Acquisition of Paladin Labs, Marketwired - 19 December 2013

UPDATE 2-Jazz Pharma to buy Italy's Gentium for $1 bln, Reuters - 19 December 2013

Abbott to Present at J.P. Morgan Healthcare Conference, PR Newswire - 19 December 2013

COVIDIEN CORPORATE NEWS

Covidien plc to Report First-Quarter Fiscal 2014 Results on January 24, 2014, Business Wire - 19 December 2013

MALLINCKRODT INDUSTRY NEWS

Prominent pain doctor investigated by DEA after patient deaths, CNN - 20 December 2013

Prescription drugs: Call to tackle addiction, BBC - 20 December 2013

Westlake doctor accused of running a "pill mill", Cleveland.com - 19 December 2013

French competition watchdog slaps Merck, Reckitt for talking down Subutex generics, FiercePharma - 19 December 2013

State Unveils Prescription Drug Abuse Strategy, News Channel 4 – Oklahoma - 19 December 2013

McKesson Corporation to Present at the 32nd Annual J.P. Morgan Healthcare Conference, Business Wire - 19 December 2013

U.S. and EU Regulators to Cooperate on Generics Inspections, FDAnews Drug Daily Bulletin - 20 December 2013

Final Glance: Pharmaceuticals companies, Associated Press - 19 December 2013

MALLINCKRODT CORPORATE NEWS

MALLINCKRODT PRODUCT NEWS

Nuvo Research® and NovaMedica sign agreement to market Pennsaid® in Russia
PRNewswire
19 December 2013

MISSISSAUGA, ON and MOSCOW, Dec. 19, 2013 /PRNewswire/ - Nuvo Research Inc. (TSX: NRI), a specialty pharmaceutical company with a diverse portfolio of products in the areas of topical pain and immunology, and NovaMedica LLC (NovaMedica), a Russian pharmaceutical company, today announced that they have signed a supply and distribution agreement providing NovaMedica the exclusive rights to market and sell Nuvo's Pennsaid 1.5% and Pennsaid 2% products in Russia and some of the Community of Independent States (CIS).

Pennsaid 1.5% and Pennsaid 2% are used to treat the symptoms and pain of osteoarthritis of the knee. Pennsaid 1.5% is approved by the U.S. Food and Drug Administration (FDA) and is currently being marketed in the U.S., Canada and certain European countries. A new drug application (NDA) for Pennsaid 2% is currently under review by the FDA which has indicated that it expects to respond to the NDA by February 7, 2014.

Under the terms of the agreement, NovaMedica is responsible for conducting required clinical studies and obtaining regulatory approval for the products in the licensed territories. Sales of Pennsaid 1.5% in Russia are projected to begin in 2015.

"With an established sales force and excellent knowledge of the Russian pharmaceutical market, NovaMedica is the ideal commercial partner to obtain approval for and market Pennsaid 1.5% and Pennsaid 2% in Russia," said Dan Chicoine, Chairman and Co-CEO of Nuvo. "Pennsaid 1.5% is currently marketed in five countries, and we will continue to expand its market potential by seeking marketing partners throughout the world."

"This agreement brings together the advanced expertise and innovative scientific potential of Nuvo Research and our clinical, regulatory and commercial capabilities in Russia, an ideal combination to bring this innovative drug to Russian and CIS patients. We expect these products have a big potential to become an effective and safe solution for unmet needs in our markets," said Fabrice Egros, COO of NovaMedica. "Our company is committed to contribute to the improvement of Russian health care and will continue to address the Russian market with innovative medicines."

http://www.prnewswire.com/news-releases/nuvo-research-and-novamedica-sign-agreement-to-market-pennsaid-in-russia-236535541.html

Back to top

MALLINCKRODT COMPETITOR NEWS

Mylan's new HQ takes global approach
Observer-Reporter
19 December 2013

When Mylan Inc.'s top executives approached Executive Chairman Robert Coury about naming the global generic pharmaceutical company's new corporate headquarters after him, Coury initially declined.

"It's not my style," Coury said Thursday during a dedication ceremony for about 200 company and public officials invited to tour Mylan's Robert J. Coury Global Center.

But as he spoke about the company's climb from a small regional generic drug company to a global player that now has 20,000 employees and a corporate goal of providing 7 billion people with access to high quality medicine, it was clear he earned the honor, something that was succinctly summed up by Chief Executive Officer Heather Bresch.

"As Mylan's CEO, Robert played an instrumental role in conceiving and executing a bold growth strategy that transformed Mylan from a U.S.-based generic pharmaceutical company into a diversified, high-quality leader in global health care," she said.

Like a lot of corporate success stories, Mylan's trek from its West Virginia and Western Pennsylvania roots to the world wasn't always an easy one, particularly when its moves as a publicly held company were placed under the scrutiny of the investment community.

"Wall Street and us – I'm sorry, I just don't share the same views as them," Coury said.

Just a few years after being excoriated by the Street for attempting to take over a pharmaceutical company more than twice its size, Coury and his staff, with the blessing of the Mylan board, decided to defy Wall Street opinion again, with far different results.

In 2007, he led the company in its transformation into a global powerhouse. At the time, Mylan was the third-largest generics manufacturing in the U.S. By purchasing India-based Matrix Laboratories, a major producer of active pharmaceutical ingredients, and also acquiring the generics business of Europe-based Merck KGaA, which gave it access to 140 countries, Mylan advanced into the top three companies in the industry on a worldwide basis.

Coury also stressed that while the moves gave Mylan its mettle as a worldwide competitor, it also helped it advance what he sees as its core mission – serving unmet needs for high-quality medicine around the world.

"We try to tell Wall Street that we try to do good, to do what's right," he said.

Bresch said the new, 280,000-square-foot global center, which received some 500 employees earlier this week, was conceived to support the company's "unique culture and ambitious objectives for growth."

Writing on the walls

During a brief tour given by Mylan employees, visitors were shown a host of features and amenities that include an open workspace design that is aimed at driving innovation and collaboration.

Some open-space lounge areas include eraser board walls that encourage employees to scribble down ideas and concepts as they meet casually.

The five-story building also features various “getaway spaces,” quiet rooms, a library, high-tech project rooms for more formal meetings, a cafe and a scalable conference center.

According to Coury, the company will need to continually encourage its employees to think creatively as it pursues its global mission.

“There is so much more to where we need to go,” he said. “China, we’re on our way. Brazil, we’re on our way.”

http://www.observer-reporter.com/article/20131219/NEWS01/131219217#.UrQSWBxvaR0

Back to top

Teva Pharmaceutical Industries Limited: Teva to Report Fourth Quarter 2013 Financial Results on February 6, 2014
Business Wire
19 December 2013

Teva Pharmaceutical Industries Ltd. (NYSE:TEVA) announced today that it will release its fourth quarter 2013 financial results on Thursday, February 6, 2014 at 7:00 a.m. ET.

Teva will host a conference call and live webcast on the same day, at 8:00 a.m. ET to discuss its fourth quarter 2013 results and overall business environment. A Question & Answer session will follow this discussion.

In order to participate, please dial the following numbers (at least 10 minutes before the scheduled start time): United States and Canada 1-888-895-5271; International 1-847-619-6547; passcode: 36341322.

A live webcast of the call will also be available on Teva's website at: www.tevapharm.com. Please log in at least 10 minutes prior to the conference call in order to download the applicable audio software.

Following the conclusion of the call, a replay of the webcast will be available within 24 hours on the Company's website. The replay can also be accessed until February 13, 2014, at 11:59 p.m. ET by calling 1-888-843-7419 or 1-630-652-3042; passcode: 36341322#.

http://www.4-traders.com/TEVA-PHARMACEUTICAL-INDUS-6492585/

Back to top

Daiichi may get Japanese experts to help Ranbaxy meet USFDA norms
The Economic Times
20 December 2013

NEW DELHI: RanbaxyBSE 0.84 % Labs' parent company Daiichi Sankyo may bring in additional teams of technical experts from Japan to help the former meet quality concerns raised by US Food and Drug Administration (FDA). Daiichi President and CEO George Nakayama, who met Commerce and Industry Minister Anand Sharma on Thursday during his visit to India is understood to have given assurance about augmenting quality measures in Ranbaxy's existing plants in India and taking corrective measures to ensure full compliance to US prescribed regulatory norms.

"They (Daiichi) would continue to extend technical assistance and bring in more experts from home country to ensure that the company's (Ranbaxy's) plants are meeting and addressing all concerns raised by US FDA," said an official in the know. A Ranbaxy spokesperson said Nakayama's meeting with Sharma was a 'courtesy visit'. Daiichi also plans to upgrade quality standards, particularly in Ranbaxy's Mohali plant, the latest facility, from which US barred products.

In September, the US FDA slapped an import alert on drugs manufactured by the company at its Mohali plant in Punjab for violation of current good manufacturing practices (GMPs).

This was the company's third plant after the Paonta Sahib (Himachal Pradesh) and Dewas (Madhya Pradesh) plants, which was red-flagged by the US drug regulator for violation of the GMP norms.

The other two plants have been facing an import alert since 2008. US drug regulator imposed the ban on two of Ranbaxy's plants months after Daiichi bought a majority stake in Ranbaxy.

In May, Ranbaxy pleaded guilty to "felony charges" for manufacturing 'adulterated' drugs at two of its Indian plants and distributing them in the US market and agreed to pay $500 million to the US government as penalty.

http://economictimes.indiatimes.com/news/news-by-industry/healthcare

Back to top

Paladin Announces Early Termination of HSR Act Waiting Period and Canadian Competition Act Compliance in Connection with Endo Health's Proposed Acquisition of Paladin Labs
Marketwired
19 December 2013

Paladin Announces Early Termination of HSR Act Waiting Period and Canadian Competition Act Compliance in Connection with Endo Health's Proposed Acquisition of Paladin Labs

MONTREAL, CANADA--(Marketwired - Dec. 19, 2013) -

Paladin Labs Inc. (TSX:PLB) ("Paladin Labs") today announced that the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended ("HSR Act") in connection with Endo Health Inc.'s ("Endo) proposed acquisition of Paladin Labs was terminated by the United States Federal Trade Commission on December 17, 2013. Paladin Labs also today announced that the Canadian Competition Bureau issued a no-action letter on December 18, 2013, which constitutes Canadian Competition Act compliance for Endo's proposed acquisition of Paladin Labs. Pursuant to the acquisition, each of Endo and Paladin Labs will be acquired by a newly-formed Irish holding company ("New Endo").

As previously announced on November 5, 2013, Endo and Paladin Labs entered into a definitive agreement pursuant to which Endo would acquire Paladin Labs in a stock and cash transaction valued at approximately $1.6 billion. The early termination of the HSR waiting period in the United States and the no-action letter obtained from the Canadian Competition Bureau in Canada satisfy conditions to the proposed acquisition. The proposed acquisition remains subject to certain conditions and approvals, including regulatory approvals (including in connection with the South African Competition Act and the Investment Canada Act), approval by shareholders of Endo and Paladin Labs, approval of the Superior Court of Quebec, registration and listing of New Endo shares and customary closing conditions.

http://online.wsj.com/article/PR-CO-20131219-911089.html

Back to top

UPDATE 2-Jazz Pharma to buy Italy's Gentium for $1 bln
Reuters
19 December 2013

* To pay $57 for each Gentium share

* Deal at a premium of 2.4 pct to Gentium's Thursday close

Dec 19 (Reuters) - Ireland-based Jazz Pharmaceuticals Plc said it would buy Italian biotech company Gentium S.p.A. for about $1 billion to get access to its lead product candidate, Defitelio, a drug used for the treatment of a rare liver condition.

The $57 per-share deal is at a premium of 2.4 percent over Gentium's Thursday close of $55.65 on the Nasdaq.

In October, the European Commission granted marketing authorization for Defitelio, which is the first drug approved for hepatic veno-occlusive disease (VOD), a rare condition in which some veins in the liver are blocked as a result of cancer therapy given prior to stem cell transplants.

The Commission last month granted Defitelio orphan drug designation for the prevention of graft versus host disease (GvHD), which entitles it to 10 years of marketing exclusivity in the European Union.

"Because Defitelio is already approved in the EU, the acquisition would add a new orphan product that has potential for short- and long-term revenue generation," Jazz Pharma CEO Bruce Cozadd said in a statement.

The company expects to develop Defitelio for approval in other indications such as prevention of VOD and acute GvHD, Jazz Pharma executives said on a conference call with analysts.

The deal, anticipated to close in the first quarter of 2014, is expected to add to Jazz Pharma's adjusted earnings in 2014 and beyond, the company said.

Gentium shareholders representing about 15 percent of the company's shares have agreed to tender their shares at the deal price, Jazz Pharma added.

Dublin-based Jazz Pharma said it expects to finance the deal with a combination of cash on hand, proceeds from a term loan and borrowings under its credit facility.

Barclays acted as financial adviser on the deal for Jazz Pharma and has provided commitment for a $500 million term loan. Gentium was advised by Jefferies LLC.

Jazz Pharma's shares, which closed at $114.72, were up 2 percent in extended trading. Gentium shares were up 3 percent.

http://www.reuters.com/article/2013/12/19/gentium-offer-jazz-idUSL3N0JY3YQ20131219

Back to top

Abbott to Present at J.P. Morgan Healthcare Conference
PR Newswire
19 December 2013

ABBOTT PARK, Ill., Dec. 19, 2013 /PRNewswire/ -- Abbott (NYSE: ABT) will present at the 32nd Annual J.P. Morgan Healthcare Conference on Tuesday, Jan. 14, 2014. Thomas C. Freyman, executive vice president, finance and chief financial officer, will make a formal presentation on the company at noon CST.

A live audio webcast of the presentation will be accessible through Abbott's Investor Relations Web site at www.abbottinvestor.com. An archived edition of the presentation will be available later that day.

http://www.sacbee.com/2013/12/19/6013626/abbott-to-present-at-jp-morgan.html

Back to top

COVIDIEN CORPORATE NEWS

Covidien plc to Report First-Quarter Fiscal 2014 Results on January 24, 2014
Business Wire
19 December 2013
DUBLIN, Dec 19, 2013 (BUSINESS WIRE) -- Covidien plc COV -.00% will report first-quarter fiscal 2014 results on January 24, 2014. The company will host a conference call for investors at 8:30 a.m. ET. The call can be accessed in the following ways:

-- Via webcast at Covidien's website: http://investor.covidien.com

-- By telephone: For both "listen-only" participants and those participants who wish to take part in the question-and-answer portion of the call, the telephone dial-in number in the U.S. is 866-318-8619. For participants outside the U.S., the dial-in number is 617-399-5138. The access code for all callers is 23284490.

-- Through an audio replay: A replay of the conference call will be available beginning at 11:30 a.m. ET on January 24, 2014, and ending at 5 p.m. on January 31, 2014. The dial-in number for U.S. participants is 888-286-8010. For participants outside the U.S., the replay dial-in number is 617-801-6888. The replay access code for all callers is 38477785.

The company will issue a news release announcing financial results for the fiscal first quarter on January 24, prior to the conference call.

http://www.marketwatch.com/story/covidien-plc-to-report-first-quarter-fiscal-2014-results-on-january-24-2014-2013-12-19?reflink=MW_news_stmp

Back to top

MALLINCKRODT INDUSTRY NEWS

Prominent pain doctor investigated by DEA after patient deaths
CNN
20 December 2013
By Stephanie Smith

Please follow link to view accompanying video: http://www.cnn.com/video/data/2.0/video/us

Salt Lake City (CNN) -- In one photograph, Carol Ann Bosley is bent precariously at the edge of the couch, asleep, her mouth still filled with food.

In another she is unconscious, her body draped over a clothes basket, clutching a tennis shoe in one hand.

For years, Roy Bosley took these and other chilling photographs of his wife to prove to her -- and her pain doctor -- that she was repeatedly overdosing on prescription painkillers.

"She'd take the pain medicine and about an hour later she would be confused, think she hadn't taken it, and take it again," said Roy Bosley, explaining how his wife's frequent overdoses began.

"We would find her unconscious various places in the house and find things like ice cream in a cupboard. The house would be a disaster, and she'd be asleep in the den."

The episodes, said Bosley, were not simple confusion about dosing.

Years after a car accident vaulted her through her car's windshield, and after multiple spine surgeries, in 2008 Carol Ann Bosley became a patient at the Lifetree Pain Clinic in Salt Lake City.

It was there, her husband said, that she got a steady and increasing supply of prescription painkillers. Soon after her first office visit, Bosley said "...she was hooked on the pain medicine, she needed it."

According to an analysis of her medical records -- by a physician retained by the Bosleys' attorney -- about a year before her death, Carol Ann Bosley was taking a painkiller and an anti-anxiety medication, amounting to around 100-120 pills per month.

By the time of her death, she was prescribed seven drugs, totaling about 600 pills per month.

'Seriously flawed'

According to the same physician, this pattern was seen with other patients who received care at Lifetree.

A separate medical malpractice claim, filed against Lifetree staff on behalf of a 42-year-old woman who died after receiving care at the clinic, describes her treatment for chronic back pain and headaches.

According to the claim, in 2001 the patient was taking "...about 200 prescription medication pills per month, equating to about 6.5 pills per day."

Seven years later, "...at the time of her death she had been prescribed 1,158 pills per month, equating to about 41.4 pills per day."

What makes the allegations against Lifetree so stunning: Before it was sold in 2010, the clinic was run for more than a decade by Dr. Lynn Webster, an anesthesiologist and pain medicine specialist who is considered a leading expert on how to safely prescribe opioids -- drugs that act on the brain to dull a person's perception of pain.

Webster is president of the American Academy of Pain Medicine and developed the "Opioid Risk Tool," a checklist to help doctors siphon out legitimate opioid users from potential abusers.

"Dr. Webster teaches a system that supposedly makes this treatment safe and effective," said Dr. Andrew Kolodny, president of Physicians for Responsible Opioid Prescribing. "But when you think about the fact that he's had multiple deaths in his clinic from overdose, it suggests that the system he is teaching is seriously flawed."

Webster, and the deaths at his now-shuttered clinic, are the subject of an ongoing investigation by the federal Drug Enforcement Administration.

CNN reached out to Webster for a response to allegations raised by former patients' family members and, through a spokesman, he declined.

According to that spokesman, who did not want to be named, Webster considers it, "...morally and ethically indefensible to comment openly on the intimate details of treatment of patients at his clinic."

But Webster did provide a statement: "It is a tragedy of the worst kind when a patient suffers from abject pain and dies, not from a result of treatment, but in spite of it.

"Those of us at Lifetree Pain Clinic who treated patients with chronic pain know this firsthand; we grieve for the patients who passed as well as their families."

Deaths among Lifetree patients, allegedly because of overprescribing, occurred against a national backdrop of skyrocketing painkiller-related overdoses.

About three people die every hour in the United States after overdosing on prescription drugs, according to the Centers for Disease Control and Prevention; most of those deaths involve prescription opioids. Utah has one of the highest drug overdose rates in the country.

What complicates the picture is an essential quandary when it comes to prescribing painkillers: They are useful when used short-term and for extreme pain, but there is no evidence that long-term use is either safe or effective.

In fact, the longer a patient takes high doses of prescription opioids, the more likely they are to become addicted and eventually overdose. Many pain management experts say overprescribing is at the heart of the overdose problem.

A recent Johns Hopkins study showed that between 2000-2010, opioid prescriptions given after pain-related doctor visits nearly doubled -- from 11% to 20% -- while identification and treatment of pain stayed the same.

"If you listen to what some of the leading pain specialists are saying today about opioids, they're saying these past 15-20 years have been a disaster," said Kolodny, a psychiatrist and chief medical officer at the Phoenix House, a nonprofit addiction treatment organization.

"We're harming far more of our patients than we're helping when we prescribe opioids aggressively."

'Zero oversight'

Aggressive prescribing practices, according to lawsuits, were common at Lifetree.

What fuels fury, and wonder, among some family members of patients who died is that the deaths are associated with a clinic run by a doctor so highly regarded in pain management circles.

"He doesn't even follow his own advice," said Bruce Webb, whose wife, Tina, died at age 39, less than two years after beginning treatment at Lifetree. "It would be really interesting to find out how many patients (at Lifetree) really died from overmedications, from overdoses."

Webb said his wife complained about migraines and jaw pain, and for years found relief with 30-pill-per-month prescriptions of Tylenol 3 and 4, painkillers containing acetaminophen and codeine.

"One day she took a little bit too much medication and felt good," said Webb. "So then she did it again, and did it again, and did it again, and then pretty soon the 30 pills wasn't working."

Tina Webb was accused of doctor shopping -- going from doctor to doctor to get multiple pain prescriptions filled -- and in 2005 was referred to Lifetree for monitoring.

When she began treatment there, it was under an agreement with the district attorney. According to a document related to her case, she "...recognizes that she has not managed her pain appropriately," and needed monitoring by a pain management clinic.

But monitoring is not what Tina Webb got at Lifetree, said Webb. She was first seen by Webster, then on subsequent visits had her care handled by a nurse practitioner.

"I was assuming that Dr. Webster was reviewing charts of (the nurse practitioners') patients, looking at how much was being prescribed and that there was some oversight," said Webb. "There was zero oversight."

Fourteen months after her first appointment at Lifetree, Webb was being prescribed a powerful cocktail of short and long-acting painkillers, sedatives and sleeping pills. According to an analysis of her medical records, by a physician retained by Webb's attorney, her dosages had increased by 600% since her first visit.

Around the same time, Bruce Webb noticed she began acting erratically and irresponsibly at home. She crashed the family car into the garage, and often would nod off at dinner while food slid off her fork.

She also became frequently, and easily, confused.

"One night she came to me, woke me up in the middle of the night and she said, 'I can't find my room, can you help me find my bed?'" said Webb. "So I had to get up, walk around, and help her get in bed. She didn't know where she was.

"The next morning I asked her, 'What was that all about?' She goes, 'What?' She had no idea, no recollection, of what had happened that night."

As his concerns grew, Webb decided to track his wife's medication. Every night after she fell asleep, he would get up and count her pills. Over the course of months he found that she was taking double -- sometimes triple -- the suggested dose.

"She was supposed to be taking six (pills) and would be taking 16," said Webb. "A whole cocktail of them, and they were all short (of the number they should have been)."

According to Tina Webb's medical records, on several occasions she went to Lifetree -- days or weeks before scheduled appointments -- to ask for an early refill. Those requests were almost always granted.

"There were obvious signs of dependence, abuse, and (a nurse practitioner at Lifetree) kept filling the prescriptions," said Webb.

'I just sobbed like a baby'

Webb said he tried contacting staff at Lifetree repeatedly to vent his concerns about his wife, and they claimed that patient privacy laws prevented them from discussing her case.

Roy Bosley said he got the same response when he tried to contact Lifetree staff, including Webster, about Carol Ann Bosley's behavior.

"When I called I said, 'I am not asking for information," said Bosley. "'I am asking to communicate critical information with regard to the well-being of my wife.' And I was given the (privacy) excuse and that was the end of it."

As the photos of Carol Ann Bosley unconscious began to stack up, so did the hospital visits after overdoses. Eventually, she was persuaded by her family and emergency room doctors to enter treatment for her addiction to painkillers.

Soon afterward, Bosley said, his wife lost weight and shed her dependence on prescription opioids, managing her pain on Tylenol only.

But just as she was adjusting to a life free of painkillers, Bosley said she got a phone call from Lifetree, requesting that the Bosleys both meet with Webster. During that meeting, Roy Bosley said Webster convinced his wife to resume taking prescription opioids.

Just over a year later, in November 2009, Carol Ann Bosley died of an overdose.

"I couldn't come back into this house for three or four weeks," after discovering his wife dead on the couch after an overdose, said Bosley. "I couldn't sleep here. It's the most horrible thing I've been through in my life."

A few weeks after she died, Roy Bosley said he was surprised to find that her death certificate listed "suicide" as the cause of death.

He said he broached the issue with the medical examiner, and was stunned by his response.

"I said, 'Why did you label it suicide?' And he says 'Well, I called Dr. Webster. He told me that she committed suicide.'"

Webster denied repeated requests by CNN to validate Bosley's claims; his spokesperson reiterated that he does not discuss patient cases.

About a month later, the cause of death on Carol Ann Bosley's death certificate was changed from "suicide" to "not determined."

Dr. Edward Leis, the medical examiner who performed Carol Ann Bosley's autopsy, denied having a conversation with Webster about her case.

He said the original determination of suicide was made based on elevated levels of prescription oxycodone and alprazolam (a painkiller and a sedative) in Carol Ann Bosley's system when she died.

Leis said the amendment to her death certificate -- although changes like that do not happen often -- took into account additional information that Bosley provided about his wife's state of mind before her death.

Similar to Carol Ann Bosley, after years of addiction, Tina Webb stopped taking painkillers. But it only lasted a month. Soon she was back at Lifetree asking to be prescribed opioids.

Reluctantly, Bruce Webb said he participated in her new treatment plan, which involved him helping to administer his wife's medication.

What he did not know -- what he said the staff at Lifetree never told him -- is that Tina had become "opiate naive." Her body could not handle pain medication at the level she was previously prescribed.

"They put her back on the same drugs, the same dose," said Webb, echoing an allegation in the lawsuit he filed against Webster and Lifetree. "So she took six pills that day (she died). That's all it took."

While her two young sons played outside in the yard in September 2007, Tina Webb lay in her bed, dead after an overdose.

"I come home from work and the boys meet me outside, say, 'Mom won't get up,'" said Webb. "I go upstairs and with the light in the room fairly dark, I knew. I went up closer to her, touched her, she was cold, stiff.

"I just sobbed. I just sobbed like a baby."

Questions linger

In depositions and in response to lawsuits brought against him, Webster has denied all allegations against him and his clinic.

A law enforcement source said it is unclear when the DEA's investigation will conclude, and whether it will find evidence of wrongdoing by Webster.

If charges are ultimately filed against him, at worst Webster could face a suspension of his DEA registration, and thus his ability to prescribe controlled substances.

Even as allegations swirl around him, Webster has said he supports -- even advocates -- alternatives to opioid-based therapy, except when it is used in a small subset of patients who benefit from it.

"Sadly, the number of people with chronic pain has exploded over the last 10 years, escalating the problem of pain to an urgent, national crisis, one which demands a direct and honest dialogue that currently is not happening," Webster's statement said. "We need safer, more effective therapies and, ultimately, need to replace opioids as a treatment method so these tragedies never happen."

Despite the allegations against him and his clinic, the American Academy of Pain Medicine, the organization headed by Webster, stands behind him.

"(Dr. Webster) is one of the country's foremost experts on the treatment of pain," said AAPM Executive Director Philip A. Saigh Jr. in a statement. "He has been a tireless advocate for the

millions of Americans who suffer from chronic pain that is so debilitating that they cannot engage in normal daily activities."

"Our staff included as many as 15 clinical professionals who treated more than 21,000 (patients) over more than 20 years," said Webster in his statement. "We treated some of the most difficult and complicated situations with people in pain and saw to it that all patients received the highest standard of care. "

Bosley and Webb have a starkly different view of Webster. They say he and his staff failed their wives.

Even years after their deaths, questions linger for both men; and the pain still smarts.

It has been particularly difficult for Webb, who has tried to make sense of the loss for his two sons.

He said, "...the heartache, the pain, the sleepless nights. It continues on. It's not done."

http://edition.cnn.com/2013/12/20/health/pain-pillar/index.html?iref=allsearch

Back to top

Prescription drugs: Call to tackle addiction
BBC
20 December 2013

GPs must start collecting anonymous data on patients who could be addicted to prescription drugs, the Commons Home Affairs Committee of MPs has said.

That would be an "important first step" in tackling the problem of up to 1.5 million possible addicts, they say.

The MPs also want to make sure more is done to stop patients visiting several doctors to feed their addiction.

Doctors' leaders said identifying people addicted to prescription drugs was "not straightforward".

Some types of painkillers and sleeping pills are among prescription drugs which can be addictive.

'Still unquantified'

The MPs said more people may be addicted to prescription drugs than to illegal drugs.

They said the abuse of such drugs was taking place "in the shadows" and much better data was required.

Committee chairman Keith Vaz said the extent of the problem was "still unquantified".

"GPs are not collating data about how many people they suspect are abusing the system," he told BBC One's Breakfast programme.

"If they start doing that and then report it amongst colleagues, that's a very important first step in trying to prevent the abuse of prescription drugs."

The committee said the NHS must do more to tackle "doctor-shopping" where an addict might visit multiple surgeries, perhaps as a temporary patient, to get more prescription drugs.

And it said authorities should be more prepared to prosecute - particularly in those cases where health professionals were supplying prescription drugs when there was no medical need.

Former prescription drug addict Barry Haslam, chairman of support group Oldham Tranx, said he had "a complete breakdown" at the age of 32 and was "put on anti-depressants and tranquillisers for 10 years".

According to the Royal College of Psychiatrists, anti-depressants are not addictive drugs like tranquillisers, alcohol or nicotine, but some users experience withdrawal symptoms.

'Devastating condition'

Mr Haslam told BBC Radio 4's Today programme that, because of "the quantity I was being prescribed, I've got a complete 10-year memory gap".

"I'm a quiet, mild accountant and they made me extremely violent - they made me into a Jekyll and Hyde character, into a real monster, which wasn't me," he added.

He said GPs, who knew how addictive some tranquillisers were, contravened guidelines by prescribing them for long periods of time.

But Richard Vautrey, deputy chairman of the British Medical Association's (BMA) GP committee, told Today "all medical professionals are very aware of the implications of the medication that they prescribe and the consequences".

"We need to be very careful about using terms like addicted when this is a complex issue," he said.

"There are a large number of people who are rightly taking medication that are controlling their symptoms, controlling their chronic pain, controlling their mental health problems.

"They need to be taking their medication and they shouldn't be stopping their medication."

'Small group'

Mr Vautrey said it would be difficult for those people "to stop without some signs of withdrawal" and "potentially they could be regarded as being addicted".

"That's very, very different from the very small group of patients that the committee have identified who potentially go doctor-shopping from practice to practice trying to get illicit drugs."

He said a system should be put in place "to identify that very small group of people".

The GP committee's chairman, Dr Chaand Nagpaul, meanwhile, said GPs already "play a key role in treating patients in the community suffering from the impact of drug addiction".

He added: "The identification of individuals addicted to prescription drugs is not straightforward and whilst we should do all we can to support their withdrawal from such drugs, we also need to ensure that patients are confident that their sensitive personal data will remain secure."

http://www.bbc.co.uk/news/uk-25458511

Back to top

Westlake doctor accused of running a "pill mill"
Cleveland.com
19 December 2013

CLEVELAND, Ohio -- Prosecutors say a Westlake doctor indicted today ran a "pill mill" that flooded the area with potent pain killers that didn't need to be prescribed.

Dr. Ronald Celeste, is charged with 226 criminal counts, including drug trafficking and illegal processing of drug documents.

Celeste, 55, was employed at West Shore Family Practice. A number for the office was disconnected Thursday. There was no answer at several phone numbers listed for Celeste.

The indictments are the result of a two-year investigation by Lakewood Police and Ohio State Pharmacy Board investigators, according to Cuyahoga County Prosecutor Timothy J. McGinty's office.

The investigation revealed that from 2009 through 2011 Celeste wrote more than 33,000 prescriptions for drugs like Oxycontin, Percocet, Codeine, Valium and other prescription painkillers that are commonly abused.

Prosecutors said that an investigation, which included undercover visits to Celeste's office, revealed he provided only superficial medical treatment.

"This activity by the doctor not only endangered his patients but also the citizens of Cuyahoga County," Assistant County Prosecutor James Gutierrez said in a release.

http://www.cleveland.com/court-justice/index.ssf/2013/12/westlake_doctor_accused_of_run.html

Back to top

French competition watchdog slaps Merck, Reckitt for talking down Subutex generics
FiercePharma
19 December 2013

European antitrust watchdogs have struck again. As Reuters reports, France's competition authority has fined Merck's ($MRK) Schering-Plough unit €15.3 million ($21 million) for a "smear campaign" against generic competitors to Subutex, a drug for opioid addiction.

Fines also went out to Merck itself (€414,000) and British supplier Reckitt Benckiser (€318,000) for their role in fighting off the Subutex generic. The Actavis ($ACT) unit that sold the copycat version, Arrow Generiques, had filed a complaint against Schering, citing the company's communications with pharmacists.

According to French officials, Schering reps not only criticized Arrow's version during sales calls but also offered discounts to pharmacists to persuade them to use the branded version instead. All of this allegedly took place in 2005; Merck bought Schering in 2009. The U.S.-based drugmaker told Reuters it's reviewing the French decision and considering its next steps.

It's just the latest move against drugmakers in Europe, where antitrust officials have been investigating the pharma industry for several years. The EU competition authority has focused on so-called "pay-for-delay" deals, under which branded drugmakers and generics companies settle patent fights with cash payments. Most recently, the agency fined Johnson & Johnson ($JNJ) and Novartis ($NVS) for their role in delaying a generic version of the painkiller fentanyl.

The French Competition Authority, on the other hand, has zeroed in on drugmakers' criticism of their generic competition. In May, the agency slapped Sanofi ($SNY) with a €40.6 million fine for disparaging a generic version of its blockbuster blood thinner, Plavix.

http://www.fiercepharma.com/story/french-competition-watchdog-slaps-merck-reckitt-talking-down-subutex-generi/2013-12-19

Back to top

State Unveils Prescription Drug Abuse Strategy
News Channel 4 – Oklahoma
19 December 2013

OKLAHOMA – A task force appointed by Governor Fallin unveiled a plan of action Thursday to help Oklahomans suffering from the state's fastest growing drug problem.

Oklahoma has the ninth-highest rate of deaths involving prescription painkillers. The campaign, called "Take As Prescribed," has several initiatives.

Among them – increasing the number of drug disposal drop boxes statewide. Increasing the sale of personal medication lock boxes to decrease drug access at home.

Enhancing the Prescription Monitoring Program (PMP), which alerts doctors if a patient is seeing several doctors to maintain their addiction.

The father of Austin Box, the OU linebacker who died from an accidental prescription overdose in 2011, said everyone can play a role.

"If you have teenagers, young adults, and you have old prescriptions around that you're not using, get rid of them," Craig Box said at the capitol, "because that's how a lot of it starts. Just access to it like that."

The Oklahoma Bureau of Narcotics has picked up 24 tons of old prescriptions from those drop boxes over the last two years.

Craig Box said if you see behavioral changes in someone, don't be afraid to ask them about what's going on in their lives.

He said you may uncover a prescription problem.

For more on the state's Take As Prescribed campaign, log on to www.kfor.com/links or www.TakeAsPrescribed.org.

http://kfor.com/2013/12/19/state-unveils-prescription-drug-abuse-strategy/

Back to top

McKesson Corporation to Present at the 32nd Annual J.P. Morgan Healthcare Conference
Business Wire
19 December 2013

SAN FRANCISCO, Dec 19, 2013 (BUSINESS WIRE) -- McKesson Corporation MCK -0.01% today announced that John H. Hammergren, the company's chairman and chief executive officer, will present at the 32nd Annual J.P. Morgan Healthcare Conference in San Francisco at 10:00 a.m. PT on Monday, January 13, 2014. Audio webcasts with accompanying slides will be available live and archived on the company's Investor Relations website at www.mckesson.com/investors . A complete listing of upcoming events for the investment community is available on the company's Investor Relations website.

http://www.marketwatch.com/story/mckesson-corporation-to-present-at-the-32nd-annual-jp-morgan-healthcare-conference-2013-12-19?reflink=MW_news_stmp

Back to top

U.S. and EU Regulators to Cooperate on Generics Inspections
FDAnews Drug Daily Bulletin
20 December 2013

U.S. and European drug regulators will work together on joint inspections around the world to help ensure access to generic medications that are both safe and effective, the FDA said.

http://www.fdanews.com/articles/161258-us-and-eu-regulators-to-cooperate-on-generics-inspections

Back to top

Final Glance: Pharmaceuticals companies
Associated Press
19 December 2013

NEW YORK -- Shares of some top pharmaceuticals companies were mixed at the close of trading:

Baxter International Inc. fell $.18 or .3 percent, to $67.06.

Bristol-Myers Squibb Co. rose $1.25 or 2.4 percent, to $53.84.

Hospira fell $.20 or .5 percent, to $41.05.

Johnson & Johnson fell $.66 or .7 percent, to $91.98.

Eli Lilly & Co. fell $.37 or .7 percent, to $50.14.

Merck fell $.11 or .2 percent, to $48.79.

Pfizer fell $.06 or .2 percent, to $30.71.

http://www.cnbc.com/id/101287730

Back to top